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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,274	09/24/2003	Andy Wolff	26486	3490

7590  
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12/29/2006

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/668,274

Applicant(s)

WOLFF ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25-50 and 52-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-50 and 52-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/10/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to applicant's amendments submitted 25 October 2006.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4,18,20-23,25-31,45,47-50, 52-63, 65-67,81-91,93-95,109, and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuma et al (US 5,584,688). Regarding claims 1-4,18,20-23,25-31,45,47-50, 52-63, 65-67,81-91,93-95,109, and 110, Sakuma et al teaches an oral device with a reservoir (3), a micropump/electronic drug release mechanism (13), and an oral anchoring element (1). It is also disclosed that the device may be refilled without surgical procedures (Fig 8) and may contain a passive release system (Fig 1).

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19,46,64 and 92 rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma in further view of Taylor et al (US 5,090,903).

Sakuma teaches the limitations of the claims as above, but fails to teach that the oral device contains more than one reservoir. Taylor teaches an oral device which contains more than one reservoir (Fig 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide more than one reservoir in order to allow the device to provide a plurality of medicaments.

5. Claims 17,44,80 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma in further view of Child (US 4,252,525).

Sakuma teaches the limitations of the claims as above, but fails to teach that there is a component which increases drug transfer through a biological barrier, such as iontophoresis. Child teaches the use of iontophoresis in an oral implant (Fig 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use iontophoresis with the implant of Sakuma in order to improve drug absorption.

6. Claims 5-16, 32-43, 68-79, and 96-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakura in further view of Pfeller et al (US 5,558,640) and Voyiazis et al (US 2004/0147906).

Sakura teaches the limitations of the claims as above, but fails to teach the use of a sensing component and a telemetry communication component. Pfeller teaches an implantable infusion device with a condition and/or status sensor (2), a processor (4), and a telemetry communication unit (8,12,16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the telemetry and sensor controls of Pfeller in order to provide an additional means to control and

communicate with the oral device. Furthermore, Voyiazis teaches these same elements within an oral device. At the time the invention was made, it was well known in the art to use these control means in an oral implant.

***Response to Arguments***

7. Applicant's arguments with respect to claims 1-23, 25-50, and 52-110 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Ellynn MacLellan*  
12/18/06

KEVIN C. SIRMONS  
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*Kevin C. Simons*